

Amendment to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1. (Previously presented) A pharmaceutical composition comprising solid microparticles comprising an agent and a matrix comprising lipid, protein, and sugar, wherein the microparticles are not liposomes, and wherein the agent is encapsulated in the matrix.
2. (Previously presented) A pharmaceutical composition comprising solid microparticles comprising an agent and a matrix, wherein the matrix comprises at least three components selected from the group consisting of lipid, protein, sugar, and synthetic polymer, wherein the microparticles are not liposomes, and wherein the agent is encapsulated in the matrix.
- 3-6. (Canceled)
7. (Original) The pharmaceutical composition of claim 1 wherein the agent is a therapeutic agent.
8. (Original) The pharmaceutical composition of claim 1 wherein the agent is a local anesthetic.
9. (Original) The pharmaceutical composition of claim 1 wherein the agent is selected from the group consisting of procaine, lidocaine, dibucaine, tetracaine, bupivacaine, mepivacaine, and articaine.

10. (Original) The pharmaceutical composition of claim 1 wherein the agent is bupivacaine.
11. (Original) The pharmaceutical composition of claim 1 wherein the agent is an anticonvulsant.
12. (Original) The pharmaceutical composition of claim 1 wherein the agent is a vasodilator.
13. (Original) The pharmaceutical composition of claim 1 wherein the agent is a protein.
14. (Original) The pharmaceutical composition of claim 1 wherein the agent is a lipid.
15. (Original) The pharmaceutical composition of claim 1 wherein the agent is a glycosaminoglycan.
16. (Original) The pharmaceutical composition of claim 1 wherein the agent is a diagnostic agent.
17. (Original) The pharmaceutical composition of claim 1 wherein the agent is a prophylactic agent.
18. (Original) The pharmaceutical composition of claim 1 wherein the lipid is a naturally occurring lipid.
19. (Original) The pharmaceutical composition of claim 1 wherein the lipid is an emulsifier.

20. (Original) The pharmaceutical composition of claim 1 wherein the lipid is a surfactant.

21. (Withdrawn) The pharmaceutical composition of claim 1 wherein the lipid is positively charged.

22. (Withdrawn) The pharmaceutical composition of claim 1 wherein the lipid is negatively charged.

23. (Original) The pharmaceutical composition of claim 1 wherein the lipid has no charge.

24. (Original) The pharmaceutical composition of claim 1 wherein the lipid is a phosphatidylcholine.

25. (Original) The pharmaceutical composition of claim 1 wherein the lipid is dipalmitoylphosphatidylcholine (DPPC).

26. (Withdrawn) The pharmaceutical composition of claim 1 wherein the lipid is polyvinyl alcohol.

27. (Original) The pharmaceutical composition of claim 1 wherein the lipid is a phospholipid.

28. (Currently amended) The pharmaceutical composition of claim 1 wherein the lipid is selected from the ~~groups~~ group consisting of phosphoglycerides; phosphatidylcholines; dipalmitoyl phosphatidylcholine (DPPC); dioleylphosphatidyl ethanolamine (DOPE); dioleyloxypropyltriethylammonium (DOTMA); dioleoylphosphatidylcholine; cholesterol;

cholesterol ester; diacylglycerol; diacylglycerolsuccinate; diphosphatidyl glycerol (DPPG); hexanedecanol; fatty alcohols; polyethylene glycol (PEG); polyoxyethylene-9-lauryl ether; a surface active fatty acid; palmitic acid; oleic acid; fatty acids; fatty acid amides; sorbitan trioleate (Span 85) glycocholate; surfactin; a poloxomer; a sorbitan fatty acid ester; sorbitan trioleate; lecithin; lysolecithin; phosphatidylserine; phosphatidylinositol; sphingomyelin; phosphatidylethanolamine (cephalin); cardiolipin; phosphatidic acid; cerebrosides; dicetylphosphate; dipalmitoylphosphatidylglycerol; stearylamine; dodecylamine; hexadecylamine; acetyl palmitate; glycerol ricinoleate; hexadecyl sterate; isopropyl myristate; tyloxapol; poly(ethylene glycol)5000-phosphatidylethanolamine; and phospholipids.

29. (Withdrawn) The pharmaceutical composition of claim 1 wherein the lipid is a derivatized lipid.
30. (Original) The pharmaceutical composition of claim 1 wherein the protein is an albumin.
31. (Withdrawn) The pharmaceutical composition of claim 1 wherein the protein is a whole cell extract.
32. (Withdrawn) The pharmaceutical composition of claim 1 wherein the protein is an antibody.
33. (Withdrawn) The pharmaceutical composition of claim 1 wherein the protein is an enzyme.
34. (Withdrawn) The pharmaceutical composition of claim 1 wherein the protein is glucose oxidase.

35. (Withdrawn) The pharmaceutical composition of claim 1 wherein the protein is insulin.

36. (Withdrawn) The pharmaceutical composition of claim 1 wherein the sugar comprises a mixture of complex and simple sugars.

37. (Original) The pharmaceutical composition of claim 1 wherein the sugar is lactose.

38. (Withdrawn) The pharmaceutical composition of claim 1 wherein the sugar is cellulose.

39. (Withdrawn) The pharmaceutical composition of claim 1 wherein the sugar is a chemically modified sugar.

40. (Withdrawn) The pharmaceutical composition of claim 1 wherein the sugar is a glycosaminoglycan.

41. (Withdrawn) The pharmaceutical composition of claim 1 wherein the sugar is dextran.

42. (Withdrawn) The pharmaceutical composition of claim 1 wherein the sugar is a chemically modified dextran.

43. (Withdrawn) The pharmaceutical composition of claim 1 wherein the sugar is chondroitin sulfate.

44. (Withdrawn) The pharmaceutical composition of claim 1 wherein the sugar is a derivatized sugar.

45. (Withdrawn) The pharmaceutical composition of claim 1 wherein the sugar is a chemically modified sugar.

46. (Previously presented) The pharmaceutical composition of claim 1 wherein the sugar is selected from the group consisting of galactose, lactose, glucose, maltose, starches, cellulose and its derivatives, methyl cellulose, carboxymethyl cellulose, fructose, dextran and its derivatives, raffinose, mannitol, xylose, dextrins, glycosaminoglycans, sialic acid, chitosan, hyaluronic acid, and chondroitin sulfate.

47. (Original) The pharmaceutical composition of claim 1 wherein the ratio of lipid to protein to sugar is approximately 3:1:1.

48. (Original) The pharmaceutical composition of claim 1 wherein the lipid comprises 0-99% of the matrix by weight.

49. (Original) The pharmaceutical composition of claim 1 wherein the lipid comprises 3-99% of the matrix by weight.

50. (Original) The pharmaceutical composition of claim 1 wherein the lipid comprises 20-60% of the matrix by weight.

51. (Original) The pharmaceutical composition of claim 1 wherein the protein comprises 0-95% of the matrix by weight.

52. (Original) The pharmaceutical composition of claim 1 wherein the protein comprises 10-30% of the matrix by weight.

53. (Original) The pharmaceutical composition of claim 1 wherein the protein comprises 1-20% of the matrix by weight.

54. (Original) The pharmaceutical composition of claim 1 wherein the sugar comprises 0-60% of the matrix by weight.

55. (Original) The pharmaceutical composition of claim 1 wherein the sugar comprises 0.5%-50% of the matrix by weight.

56. (Original) The pharmaceutical composition of claim 1 wherein the sugar comprises 10-30% of the matrix by weight.

57. (Original) The pharmaceutical composition of claim 1 wherein the microparticles are less than 50 micrometers in diameter.

58. (Original) The pharmaceutical composition of claim 1 wherein the microparticles are less than 10 micrometers in diameter.

59. (Original) The pharmaceutical composition of claim 1 wherein the microparticles are less than 5 micrometers in diameter.

60. (Original) The pharmaceutical composition of claim 1 wherein the microparticles are less than 1 micrometer in diameter.

61. (Original) The pharmaceutical composition of claim 1 wherein the microparticles are less than 500 nanometers in diameter.

62. (Original) A method of preparing microparticles comprising an agent encapsulated in a lipid-protein-sugar matrix, the method comprising steps of:

providing an agent;

contacting the agent with a lipid, a protein, and a sugar; and

spray drying mixture of the agent, the lipid, the protein, and the sugar to make microparticles.

63. (Previously presented) A method of administering an agent, the method comprising steps of:

providing a patient;
providing solid microparticles of an agent encapsulated in a lipid-protein-sugar matrix, wherein the microparticles are not liposomes; and
administering the microparticles to the patient.

64. (Original) The method of claim 63 wherein the step of administering comprises injecting the microparticles into the patient.

65. (Original) The method of claim 63 wherein the step of administering comprises placing the microparticles in a body cavity of the patient.

66-79. (Canceled)

80. (Previously presented) The pharmaceutical composition of claim 1 wherein the microparticles range from 3 microns to 5 microns in diameter.

81. (Previously presented) The pharmaceutical composition of claim 2 wherein the matrix comprises a lipid, a protein, a sugar, and a synthetic polymer.

82-83. (Canceled)

84. (Previously presented) The pharmaceutical composition of claim 1, 2, or 6, wherein the microparticles are prepared by spray drying.

85. (Currently amended) A solid microparticle comprising an agent and a matrix comprising lipid, protein, and sugar, wherein the agent is encapsulated by in the matrix, whereby the microparticle is prepared by spray drying.

86. (New) A pharmaceutical composition comprising solid microparticles, wherein the microparticles are not liposomes, comprising:

(a) a matrix comprising:

- (i) a lipid selected from the group consisting of phosphoglycerides; phosphatidylcholines; dipalmitoyl phosphatidylcholine (DPPC); dioleylphosphatidyl ethanolamine (DOPE); dioleyloxypropyltriethylammonium (DOTMA); dioleoylphosphatidylcholine; cholesterol; cholesterol ester; diacylglycerol; diacylglycerolsuccinate; diphosphatidyl glycerol (DPPG); hexanedecanol; fatty alcohols; polyethylene glycol (PEG); polyoxyethylene-9-lauryl ether; a surface active fatty acid; palmitic acid; oleic acid; fatty acids; fatty acid amides; sorbitan trioleate (Span 85) glycocholate; surfactin; a poloxomer; a sorbitan fatty acid ester; sorbitan trioleate; lecithin; lysolecithin; phosphatidylserine; phosphatidylinositol; sphingomyelin; phosphatidylethanolamine (cephalin); cardiolipin; phosphatidic acid; cerebrosides; dicetylphosphate; dipalmitoylphosphatidylglycerol; stearylamine; dodecylamine; hexadecyl-amine; acetyl palmitate; glycerol ricinoleate; hexadecyl sterate; isopropyl myristate; tyloxapol; poly(ethylene glycol)5000-phosphatidylethanolamine; and phospholipids;
- (ii) a sugar selected from the group consisting of galactose, lactose, glucose, maltose, starches, cellulose and its derivatives, methyl

cellulose, carboxymethyl cellulose, fructose, dextran and its derivatives, raffinose, mannitol, xylose, dextrins, glycosaminoglycans, sialic acid, chitosan, hyaluronic acid, and chondroitin sulfate; and

(iii) a protein; and

(b) an agent, wherein the agent is encapsulated in the matrix.

87. (New) The pharmaceutical composition of claim 86, wherein the lipid is dipalmitoyl phosphatidylcholine (DPPC).

88. (New) The pharmaceutical composition of claim 86, wherein the protein is albumin.

89. (New) The pharmaceutical composition of claim 86, wherein the sugar is lactose.

90. (New) A pharmaceutical composition comprising solid microparticles, wherein the microparticles are not liposomes, comprising:

(a) a matrix comprising:

(i) dipalmitoyl phosphatidylcholine (DPPC);

(ii) lactose; and

(iii) albumin; and

(b) an agent, wherein the agent is encapsulated in the matrix.

91. (New) The pharmaceutical compositions of any one of claims 1, 86, and 90, wherein the ratio of lipid to protein to sugar is approximately 3:1:1.

92. (New) The pharmaceutical compositions of any one of claims 1, 86, and 90, wherein the ratio of lipid to protein to sugar to agent is approximately 54:18:18:10.

93. (New) The pharmaceutical compositions of any one of claims 1, 86, and 90, wherein the lipid comprises 20-60% of the matrix by weight; wherein the protein comprises 10-30% of the matrix by weight; and wherein the sugar comprises 10-30% of the matrix by weight.

94. (New) A pharmaceutical composition comprising solid microparticles comprising an agent and a matrix comprising lipid, protein, and sugar; wherein the microparticles are not liposomes; wherein the agent is encapsulated in the matrix; and wherein the ratio of lipid to protein to sugar is approximately 3:1:1.

95. (New) A pharmaceutical composition comprising solid microparticles comprising an agent and a matrix comprising lipid, protein, and sugar; wherein the microparticles are not liposomes; wherein the agent is encapsulated in the matrix; and wherein the ratio of lipid to protein to sugar to agent is approximately 54:18:18:10.

96. (New) The pharmaceutical compositions of any one of claims 1, 86, and 90, wherein the agent is a small molecule.

97. (New) The pharmaceutical compositions of any one of claims 1, 86, and 90, wherein the agent is a protein.